DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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Food and Drug Administration
Rockville MD 20857

WARNING LETTER

Ref. No. 03-HFD-314-01

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

OCT 22 2002

Mr. Will Block, President
Life Enhancement Products, Inc.
P.O. Box 751390
Petaluma, California 94975-1390

Dear Mr. Block:

This letter concerns your firm's marketing and distribution of the product "GalantaMind," labeled as containing "Galantamine hydrobromide extract 8mg."

The "GalantaMind" label states that it is "a galantamine dietary supplement." FDA does not believe that this product is eligible to be classified as a "dietary supplement" under section 201(ff)(3)(B)(ii) of the Federal Food, Drug, and Cosmetic Act [21 USC § 321 (ff)(3)(B)(ii)] ("the Act"). That provision states:

> "The term 'dietary supplement' ... does not include ... (ii) an article authorized for investigation as a new drug ... for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public, which was not before such approval, certification, licensing, or authorization marketed as a dietary supplement or as a food ..."

Promotional literature for your product announced that it was introduced in October 2000. However, the authorization of galantamine for investigation as a new drug had already been disclosed in 1997 by several disclosures in "The Pink Sheet" that made public the clinical trials being done by Janssen Pharmaceutica Products whose product, Reminyl, is now the subject of an approved NDA. Your article "Fight Alzheimer's Disease," also mentions galantamine being used in clinical trials in 1985. FDA has found no information indicating that galantamine was marketed as a food or dietary supplement before its authorization for investigation as a new drug. If, as appears to be the case, galantamine had already been investigated in clinical trials and those trials made public before October 2000, and galantamine was not marketed as a food or dietary supplement before its authorization for investigation as a new drug, your product would not be eligible for treatment as a "dietary supplement."

Statements found on your Internet website (www.life-enhancement.com), where "GalantaMind" is offered for sale, indicate that "GalantaMind" is intended to prevent or treat disease or affect the structure or function of the body. Examples of the disease and structure/function claims made for your product on your website include the following:

- the article entitled "Revive Your Memory" discusses decline in memory function and the pharmacological activity of galantamine and "GalantaMind" in preventing or treating memory loss and restoring memory function;

- the title of the article "Fight Alzheimer's Disease" is a disease claim because it claims to treat a disease state. The article discusses Alzheimer's disease and its treatment using galantamine. The same article claims that galantamine can successfully treat chronic fatigue syndrome and fibromyalgia, and implies that galantamine reverses alcohol-induced learning decline;

- the article "Boost Memory and Keep It" discusses galantamine's role in preventing or treating Alzheimer's disease, comparing its effectiveness to drugs like Aricept and Tacrine. This article also discusses galantamine's use for a variety of neurological, ophthalmological, gastrointestinal, cardiological, and physiotherapeutic purposes;

- the article "Galantamine: Food for Mind and Body" claims that galantamine "prevent[s] Alzheimer's-related memory loss," "combats fatigue syndromes," and "may help overcome impotence"; and

- the title of the article "Galantamine Beats Prescription Drugs for Combating Mental Decline" is a disease claim. The article goes on to discuss galantamine and "GalantaMind"'s effectiveness in treating dementia and Alzheimer's disease.

Your product also has the potential to cause serious and life-threatening adverse events. The labeling for "GalantaMind" provides virtually no information about the risks associated with taking galantamine, and the dose titration regimes suggested in the labeling caused a higher frequency of potentially serious adverse events in clinical trials involving similar dose titration regimes for Reminyl.

Based on the above, "GalantaMind," which contains the ingredient galantamine hydrobromide is a drug as defined in section 201(g) of the Act. Moreover, it is also a "new drug" under section 201(p) of the Act because there is no evidence that this product is generally recognized as safe and effective for its intended use. As a "new drug," "GalantaMind" may not be legally marketed in the United States without an approved new drug application pursuant to section 505(a) of the Act.

The drug is also misbranded under section 502(f)(1) of the Act because the labeling fails to bear adequate directions for use for the conditions for which it is offered.

We request your response to the following questions:

1. An estimate of the quantities of the drug manufactured or received within the past twelve (12) months.

2. An estimate of the size and frequency of shipments made in the past twelve (12) months.

3. An estimate of the amount of the drug that is in inventory under your control and your estimate of the amount in distribution channels outside your control.

4. The date of discontinuance in the event you have already stopped marketing this drug product.

5. Your intentions with respect to the disposition of your inventories and outstanding stocks in trade channels.

This letter is not intended to be an all-inclusive review of all labeling and products your firm markets. It is your responsibility to ensure that all products marketed by your firm are in compliance with the Act and its implementing regulations.

We request that you take prompt action to correct these violations. Failure to promptly correct violations may result in enforcement action being initiated by the Food and Drug Administration without further notice. The Federal Food, Drug, and Cosmetic Act provides for the seizure of illegal products and for injunction against the manufacturer and/or distributor of illegal products.

Please notify this office in writing within fifteen (15) working days of receipt of this letter as to the specific steps you have taken to correct the stated violations. You should also include an explanation of each step being taken to identify and make corrections to assure that similar violations will not recur. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be implemented.

Your reply should be sent to the attention of the undersigned at the above letterhead address.

Sincerely,

David J. Horowitz, Esq.
Director
Office of Compliance
Center for Drug Evaluation and Research